

## **REMARKS/ARGUMENTS**

Reconsideration of the application is respectfully requested.

### **I. Status of the Claims**

Claims 1-6 are presently pending. Claim 1, 2, 3, 4, and 6 are amended to recite "crystal form." Claim 3 is amended to recite "spontaneous nucleation," an art-recognized term. No new matter is introduced. Support for the amendments may be found, for example, with reference to Applicant's specification at p. 7, lines 15-17.

### **II. Claims Rejections under 35 U.S.C. § 112**

Claims 1-6 are rejected under 35 U.S.C. § 112, second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Accordingly to the Examiner, claims 1 and 2 are rejected for failing to distinguish or further limit the claim(s) reciting the X-ray data. Specifically, the Examiner contends that claims 1 and 2 appear to be substantial duplicates as the only difference between the two are added X-ray data. Claim 2 has been canceled. Therefore, Applicant contends that the Examiner's argument is moot with this amendment, and respectfully requests withdrawal of the rejection.

According to the Examiner, claims 1 - 4, and 6 are rejected for reciting "a crystal," which, as the Examiner points out, will disclose an invention that is a single particle. Claims 1 - 4 and 6 have been amended to recite "crystal form." Therefore, Applicant contends that the Examiner's argument is moot with this amendment, and respectfully requests withdrawal of the rejection.

According to the Examiner, claim 3 contains the term "spontaneous nucleus" which is not an art-recognized term. Claim 3 has been amended to recite the term "spontaneous nucleation," a term which the Examiner noted was supported by the discussion in the specification at and which is art-recognized. Therefore, Applicant

contends that the Examiner's argument is moot with this amendment and respectfully requests withdrawal of the rejection.

### **III. Claims Rejections under 35 U.S.C. § 102**

Claim 6 is rejected under 35 U.S.C. § 102(b) as being anticipated by Kakemi, et al., "*Chemical Structure, Physico-chemical Properties and Stability of Prulifloxacin*," Iyakuin Kenkyu Vol. 28, No 1, 20 January 1997, pages 1-11; page 4, 2.1 Kessho Takei no ko ("Kakemi"). The Examiner states that Kakemi discloses form III of prulifloxacin (A) and that crystal form III is obtained directly from recrystallization of A by using acetonitrile. The Examiner alleges that it would be reasonable for one of ordinary skill in the art to infer that standard isolation procedures were followed in Kakemi, which include drying of the product by heating and/or under reduced pressure. The Examiner contends that the Applicant relies on conventional procedures for the desolvation step of the acetonitrile solvate of A (B), which would include the same procedure used in routine isolation.

Applicant respectfully traverses the argument. Kakemi states that compound A was recrystallized from acetonitrile and that three crystal forms were obtained, depending on the crystallization conditions. These forms were Form I, Form II, and Form III of type A. (Kakemi, p. 7). In contrast, Applicant states in their specification that they could not obtain any type III crystals of compound A when recrystallizing directly from a supersaturated solution of compound A and acetonitrile. (Specification, p. 5, Experimental Example 1). When using the process recited in Kakemi, Applicant produces the acetonitrile solvate of A (B). The Examiner assumes that compound B is formed in the methods recited in Kakemi, but there is no support for that assumption. Kakemi does not disclose supersaturation conditions or the production of only type I and II crystals and compound B under varying recrystallizing conditions. Finally, it would not be reasonable for one of ordinary skill in the art to infer that desolvating compound B under any conditions, standard or not, would only produce the type III form of compound A. For the above reasons, Applicant respectfully requests the present rejections be withdrawn.

**CONCLUSION**

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

Dated: September 25, 2008

Respectfully submitted,

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